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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,575	07/30/2003	Lawrence M. Tsal	CV0323 NP	8662
26079 7590 08/29/2007 BRISTOL-MYERS SQUIBB COMPANY 100 HEADQUARTERS PARK DRIVE SKILLMAN, NJ 08558			EXAMINER REICHLE, KARIN M	
			ART UNIT 3761	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/630,575

Applicant(s)

TSAL ET AL.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 12, 17, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 11-12, 17 and 23-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-1-07 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. Claims 1, 11-12, 17 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 now requires a part of a curved periphery opened by a fastener have a length which permits folding of an outer pouch wall and unhindered access to a separable coupling. Applicant relies upon page 17, line 8-9 for support of such claimed subject matter. However, while page 17, lines 1-9 set forth that a zipper fastener may extend for at least half of the periphery of the outer pouch to allow the inner pouch to be easily inserted into or removed from the outer pouch and such length may also provide substantially unhindered access to the first fastener for removably securing the inner pouch in position, this is not what is claimed. If Applicant maintains such claim language, the portion of the application as originally filed which

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provides support for the entire scope of each claim in a single embodiment should be set forth.

See also paragraph 3.

### ***Claim Language Interpretation***

3. The terminology “periphery” as defined by the dictionary is “the external boundary or surface of a body”. The terminology “along” is defined by the dictionary as “in a line parallel with the length or direction of”. With regard to the last four lines of claim 1, see MPEP 2163.06, I.

### ***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 11-12, 17 and 23-24 are rejected under 35 U.S.C. 103 as being unpatentable over Sato et al ‘695 in view of Hulett ‘553 and Morton ‘241.

Claim 1: See Figures, esp. 1a-1d and 6, and note the curved periphery of the outer pouch in longitudinal cross-section and the spacing of edges of end 13 between longitudinal side edges when opened as compared to when closed and col. 4, line 61-col. 5, line 25, col. 6, line 55-col. 7, line 61 and col. 1, lines 12-27 of Sato, i.e. Sato teaches an ostomy pouch, see Figures and col. 7, lines 28-34, for receiving human body waste from a stoma having inner and outer pouches, 15 and 10, the outer pouch includes a curved periphery, see, e.g., Figures 1b-1d, i.e. walls are curved from bottom of pouch to adjacent the mouth at end 13, and a fastener 14 on a portion of the curved periphery, see Figure 1a or Figures 1b-1d, e.g. 14 is on a portion of the curved

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periphery, e.g. the edge of the curved wall 10 adjacent 14 in the Figures 1b-1d directed into the page or the lower of the two solid lines at the top of Figure 1a, configured to permit re-closeable opening of the outer pouch “along” a curved part of the curved periphery, i.e. permits opening along the curved wall 10 adjacent 14, for replacement of the inner pouch. (It is noted that the claim still does not require the fastener be “along” such curved part or travel along a curved path which path defines a curved portion of the periphery which also defines the opening. However, note the edges of end 13 are spaced apart at longitudinal centerline but not at longitudinal side edges when end is opened as well the discussion infra of 1) and 2).) The outer pouch is attachable to the body and includes a first aperture for accommodating a stoma, and the inner pouch includes a second aperture at least partly aligned for communication with the first aperture when said inner and outer pouches are in an operative position, the inner pouch being removably securable directly or indirectly to the outer pouch by a separable coupling, see Figures 1a-1d and col. 6, line 55-col. 7, line 27. The separable coupling permits replacement of the inner pouch by a replacement inner pouch, see col. 7, lines 28-61. Applicant claims 1) the fastener for reclosable opening of a pouch being a sliding zipper fastener and now also claims 2) the curved part of the curved periphery opened by the fastener have a length which permits folding of an outer pouch wall and unhindered access to the separable coupling. With respect to 1) while Sato et al teaches a pouch having a fastener, it does not teach such fastener being a sliding zipper fastener. Note however claim 6 and col. 10, lines 15-18 thereof. Furthermore see Hulett ‘553 at the Figures and col. 2, lines 6-23 and 36-40 and col. 3, line 30-35 as well as Morton ‘241 at Figures 5-6B (Note especially the edges of the end in 6B which are spaced apart at longitudinal centerline but not at longitudinal side edges when end is opened so as to be curved or folded

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apart), the title and col. 6, line 30-col. 7, line 13 (i.e. '241 teaches interchangeability of openable/closable ostomy pouch mouth with openable/closable ostomy pouch mouth with a slider 31 and a track, i.e. the portion of the outer portion of the mouth complementary to structure 32). Therefore, to make the pouch reclosable opening fastener of Sato a pouch reclosable opening fastener as taught by Hulett and Morton instead, i.e. of the sliding zipper type, would either be obvious, see *In re Siebentritt*, 54 CCPA 1083, i.e. two equivalents are interchangeable for their desired function, express suggestion of desirability of substitution not needed to render such substitution obvious, or obvious in view of the interchangeability as taught by Morton. Note also the discussion of claims 23-24 *infra*. With regard to 2), it is the Examiner's first position that a curved part of the curved periphery opened by the fastener has a length which permits folding, i.e. the mouth defined by the edges of 13 when opened is rounded/folded/curved, of the outer pouch and unhindered access to the separable coupling, i.e. see Figure 1d and compare size of mouth to that of Figure 1c as well as Figures 1b and 6 which show access from mouth to coupling which is unhindered. In any case, i.e. the Examiner's second position, note again Figure 6B of '241 esp. compared to Figure 6A of '241, i.e. curving/rounding/folding of mouth, and cited Figures of Sato, i.e. a pathway which is unblocked between mouth and coupling. Therefore, the prior art combination necessarily and inevitably teaches a curved part of the curved periphery opened by the fastener has a length which permits folding, i.e. curving, of the outer pouch and unhindered access to the separable coupling.

Claim 11: See col. 6, line 55-col. 7, line 61. It is noted that the portion of the coupling which is adhesive has not been specifically claimed.

Claim 12: See discussion of claim 1 and col. 7, lines 54-56 of Sato again.

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Claim 17: See col. 5, lines 11-17 and col. 7, lines 54-56 of Sato.

Claim 23: The sliding zipper fastener of '241 includes at least one curved zipper track and a movable slider, i.e. the portion of the outside of the pouch opposite 32 and 31, respectively, and the slider includes one or more curved zipper track engaging surfaces 32 having a characteristic to accommodate the slider along the curved zipper track, i.e. the curvature of the portion opposite 32 in Figure 5. It is noted that the dimension of the track which is curved still has not been specified. However the prior art teaches curvature in several dimensions, see, e.g., Figure 5 as well as Figure 6B of '241.

Claim 24: See the discussion of claim 23 and note the track/portion opposite 32 is not toothed. Note also Figure 4D and col. 6, line 33, i.e. "curvilinear".

### ***Response to Arguments***

6. Applicant's remarks have been considered but are either deemed moot in that the issue discussed has not been repeated or not persuasive for the reasons set forth supra. It is noted that Applicant's arguments with regard to the combination of teachings is deemed narrower than the prior art teachings, i.e. all the references teach a pouch having an opening with a reclosable fastener to allow access to contents inside the pouch.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Karin M. Reichle  
Primary Examiner  
Art Unit 3761

KMR  
August 20, 2007